

REMARKS

The specification has been amended to reflect the national stage status.

The claims have been amended to remove the multiple dependencies in order to reduce the PTO filing fee and remove the improper multiple dependencies.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "Version with markings to show changes made".

Favorable action on the merits is solicited.

Respectfully submitted,

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DESCRIPTION

SOLID PREPARATION CONTAINING CHITOSAN POWDER AND PROCESS FOR PRODUCING THE SAME

5 *This application is a 371 of PCT/JP00/05279 filed August 7, 2000.*

TECHNICAL FIELD

The present invention relates to a colonic delivery solid preparation, more particularly a colonic delivery solid preparation containing chitosan powder designed to pass through the stomach or 10 the small intestine without disintegration, but to disintegrate in the large intestine and release a medicament therefrom when administered orally, and further relates to a sustained release solid preparation containing chitosan powder designed to partly disintegrate in the stomach and release a part of the medicament therefrom, to release the medicament in the small intestine without disintegration, and after 15 passing through the small intestine, to disintegrate at an accelerated rate in the large intestine whereby the remaining medicament in the preparation is released in the large intestine.

20 BACKGROUND ART

Chitosan is a natural polymer which is obtained by N-deacetylation of a polysaccharide chitin in a conc. alkaline solution, said chitin being present in abundance in the exoskeleton of crustaceans or insects, and chitosan per se has been used as a colonic delivery 25 substance because it disintegrates specifically by *Escherichia coli*. Several pharmaceutical compositions containing chitosan, which can

C L A I M S

1. A colonic delivery solid preparation containing chitosan powder, which is produced by coating a medicament-containing solid material successively with (1) a water-insoluble polymer having a chitosan powder dispersed therein, and (2) an enteric polymer.

5 2. A solid preparation according to claim 1, wherein the water-insoluble polymer is selected from the group consisting of ethyl cellulose, ethyl acrylate-methyl methacrylate-trimethylammoniummethyl 10 methacrylate chloride copolymer and methyl methacrylate-ethyl acrylate copolymer.

15 ✓ 3. (Amended) A solid preparation according to claim 1 ~~or 2~~, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose acetate succinate, hydroxypropyl methylcellulose phthalate and methacrylic acid-ethyl acrylate copolymer.

✓ 4. (Amended) A solid preparation according to ~~any one of claims 1 to 3~~, wherein the weight ratio of the chitosan powder to the water-insoluble polymer is in the range of about 1:10 to about 10:1.

✓ 5. (Amended) A solid preparation according to ~~any one of claims 1 to 4~~, which is in a form selected from the group consisting of a pellet, a capsule, and a tablet.

20 6. A process for producing a colonic delivery solid preparation containing chitosan powder, which comprises coating a medicament-containing solid material with a solution containing a water-insoluble polymer having a chitosan powder dispersed therein, and further by 25 coating the resultant with an enteric polymer.